CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (Proposition 65)

NOTICE TO INTERESTED PARTIES May 14, 2004

REQUEST FOR COMMENTS ON PROPOSED LISTING OF ARISTOLOCHIC ACIDS AND HERBAL REMEDIES CONTAINING PLANT SPECIES OF THE GENUS *ARISTOLOCHIA* AS KNOWN TO CAUSE CANCER

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code section 25249.5 *et seq.*, Proposition 65). OEHHA is proposing to include "aristolochic acids" and "herbal remedies containing plant species of the genus *Aristolochia*" on the list of chemicals known to the state to cause cancer, for purposes of Proposition 65.

Health and Safety Code section 25249.8(a) requires that certain substances identified by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP), as described in Labor Code sections 6382(b)(1) and (d), be included on the Proposition 65 list. Labor Code section 6382(b)(1) references substances identified as human or animal carcinogens by IARC, and Labor Code section 6382(d) references substances identified as carcinogens or potential carcinogens by IARC or NTP. Aristolochic acids were identified by IARC as animal carcinogens. Herbal remedies containing plant species of the genus *Aristolochia*, were identified by IARC as carcinogenic to humans.

In 2002, IARC issued the monograph *Some Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene* (Volume 82) in its series *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans.* In this monograph, IARC concluded "there is *sufficient evidence* in experimental animals for the carcinogenicity of aristolochic acids." In addition, IARC classified herbal remedies containing plant species of the genus *Aristolochia* as "carcinogenic to humans (Group 1)."

Pursuant to state law IARC's designation of aristolochic acids as animal carcinogens and of herbal remedies containing plant species of the genus *Aristolochia* as carcinogenic to humans means that "aristolochic acids" and "herbal remedies containing plant species of the genus *Aristolochia*" must be included on the Proposition 65 list (Labor Code sections 6382(b)(1) and (d)). Therefore, OEHHA proposes to add "aristolochic acids" and "herbal remedies containing plant species of the genus *Aristolochia*" to the Proposition 65 list of chemicals known to cause cancer. Anyone wishing to provide comments as to whether "aristolochic acids" and "herbal remedies containing plant species of the genus

Aristolochia" meet the requirements for listing as causing cancer specified in Health and Safety Code section 25249.8(a), by reference to Labor Code sections 6382(b)(1) and (d), should send written comments in <u>triplicate</u>, along with any supporting documentation, by mail or by fax to:

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Office of Environmental Health Hazard Assessment
Street Address: 1001 I Street
Sacramento, California 95814
Mailing Address: P.O. Box 4010
Sacramento, California 95812-4010

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Comments may also be delivered in person or by courier to the above address. It is requested, but not required, that written comments and supporting documentation by transmitted via email addressed to: coshita@oehha.ca.gov. In order to be considered, comments must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered, sent by FAX, or transmitted electronically) by 5:00 p.m. on June 14, 2004.